

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

The effect of capsule contain cumin essential oil on weight and metabolic profiles of obese and overweight patients and its comparison with orlistat

Protocol summary

Study aim

The aim of this study is to determine the effects of cumin capsules and orlistat on weight changes and metabolic profiles in patients with overweight and obese.

Design

Randomized double-blind placebo-controlled trial.

Settings and conduct

Among patients with overweight referred to the Naghavi Clinic affiliated to Kashan Medical Sciences University, Kashan, Iran, 87 patients will be selected. The study will be double blind in which participants and investigators/the assessors of the outcomes are unaware of the study groups and drug and placebo are similar. Fasting blood samples will be taken at baseline and 8 weeks after the intervention. Intervention period: 8 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Overweight (Body mass index range: 25.2–48.8 kg/m²) and subjects aged 18–60. Exclusion criteria: Those with malignancy, metabolic, thyroid or cardiovascular disorders, pregnancy and lactation, and those using hormonal, antidiabetic, or anti-obesity medications.

Intervention groups

Intervention group 1: Cumin essential oil capsule (Barij Essence pharmaceutical company, Kashan, Iran), orally, three times a day, for 8 weeks. Intervention group 2: Orlistat capsule (Hoffmann-La Roche Co, Munich, Germany), orally, three times a day, for 8 weeks. Control group: Placebo capsule (Barij Essence pharmaceutical company, Kashan, Iran), orally, three times a day, for 8 weeks.

Main outcome variables

Weight change

General information

Reason for update

Due to an error, the request for an update in our website

has been conducted after paper published. However, the revisions were in accordance with either the original approved proposal or with coordination with Vice Chancellor of Research at the University.

Acronym

IRCT registration information

IRCT registration number: **IRCT2014043012438N8**

Registration date: **2014-05-20, 1393/02/30**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-18, 1399/09/28**

Update count: **1**

Registration date

2014-05-20, 1393/02/30

Registrant information

Name

Mohsen Taghizadeh

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Barij Research Center of Medicinal Herbs

Expected recruitment start date

2014-04-27, 1393/02/07

Expected recruitment end date

2015-05-15, 1394/02/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of capsule contain cumin essential oil on weight and metabolic profiles of obese and overweight patients and its comparison with orlistat

Public title

The effect of cumin pearl on treatment of obesity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Overweight (Body mass index range: 25.2-48.8 kg/m²)
Aged 18-60

Exclusion criteria:

Those with malignancy Metabolic disorders Thyroid disorders Cardiovascular disorders Pregnancy and lactation Those using hormonal, antidiabetic, or anti-obesity medications

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **87**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned into three groups. A list of random numbers from 1 to 87 using a random number generator (<https://stattrek.com/statistics/random-number-generator.aspx>) will be generated, and then patients will be randomly assigned using numbers into three groups. At study baseline, after stratification for gender, pre-intervention body mass index and age, subjects were randomly assigned to three groups. Randomization will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Clinic, who is not involved in the trial and not aware of random sequences, will assign the participants to the numbered bottles of drugs. Placebo capsules contained microcrystalline cellulose and were packed in identical capsules with drugs, and coded by Barij Essence Pharmaceutical company to guarantee blinding. Patients and researcher will not know the type of intervention. After analyzing the data, pocket codes will be decoded. Participants and investigators/the assessors of the outcomes are unaware

of the study groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8715988141

Approval date

2014-04-26, 1393/02/06

Ethics committee reference number

633/1/5/29/ب

Health conditions studied

1

Description of health condition studied

Obesity and overweight

ICD-10 code

E66

ICD-10 code description

Obesity

Primary outcomes

1

Description

Weight change

Timepoint

Baseline and end of study

Method of measurement

Scale

Secondary outcomes

1

Description

Total cholesterol

Timepoint

Baseline and end of study

Method of measurement

Enzymatic kit

2**Description**

Insulin

Timepoint

Baseline and end of study

Method of measurement

ELISA kit

3**Description**

Triglycerides

Timepoint

Baseline and end of study

Method of measurement

Enzymatic kit

4**Description**

HDL-cholesterol

Timepoint

Baseline and end of study

Method of measurement

Enzymatic kit

5**Description**

LDL-cholesterol

Timepoint

Baseline and end of study

Method of measurement

Enzymatic kit

6**Description**

Glutathione

Timepoint

Baseline and end of study

Method of measurement

Spectrophotometry

7**Description**

Fasting plasma glucose

Timepoint

Baseline and end of study

Method of measurement

Enzymatic kit

8**Description**

Insulin resistance

Timepoint

Baseline and end of study

Method of measurement

Calculation using HOMA formula

9**Description**

Thyroid hormones

Timepoint

Baseline and end of study

Method of measurement

ELISA kit

10**Description**

Total antioxidant capacity

Timepoint

Baseline and end of study

Method of measurement

Spectrophotometry

Intervention groups**1****Description**

Intervention group 1: Cumin essential oil capsule (Barij Essence pharmaceutical company, Kashan, Iran), orally, three times a day, for 8 weeks.

Category

Treatment - Drugs

2**Description**

Intervention group 2: Orlistat capsule (Hoffmann-La Roche Co, Munich, Germany), orally, three times a day, for 8 weeks.

Category

Treatment - Drugs

3**Description**

Placebo capsule (Barij Essence pharmaceutical company, Kashan, Iran), orally, three times a day, for 8 weeks.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Naghavi clinic affiliated to Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

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Shahid Rajaei Avenue, Kashan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Kashan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr Mohsen Taghizadeh
Position
Associate professor
Latest degree
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Other areas of specialty/work

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Person responsible for updating data

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Fax**Email**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available